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A ball-slide-type interbody distractor is effective in posterior reduction and internal fixation for patients with mid- to high-grade isthmic spondylolisthesis enrolled in a randomized clinical trial

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Abstract

Study Design: Clinical and radiographic results of a randomized, controlled, double-blind clinical trial

Objective: To investigate the clinical applicability of a ball-point slide-type interbody distractor in posterior reduction and internal fixation for mid- to high-grade isthmic spondylolisthesis.

Summary of Background Data: Posterior reduction and internal fixation is the effective treatment for spondylolisthesis. However, for the mid and high-grade isthmic spondylolisthesis patients with the conditions of vertebral osteoporosis and extremely narrow intervertebral space, the reduction is difficult; post-surgery intervertebral space height lost becomes serious; the fracture and loosening rate of fixation system is higher. No study regarding the prevention of these adverse outcomes in this technique is reported.

Methods: A total of 59 patients of mid and high-grade isthmic spondylolisthesis were randomly divided into random groups (investigational group and control group) applying simple randomized method in this study. In addition, 30 patients received posterior reduction and internal fixation as control. Twenty-nine patients received posterior reduction and internal fixation by ball-point slide-type interbody distractor were assigned to the investigational group. X-ray examination was performed before and after operation. The degree of reduction, height of intervertebral space were compared. The preoperative and postoperative Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) were evaluated. Additionally, rate of the fixation system fracture was also assessed.

Results: Before treatment, there were no significant differences in ISH ($P = .72$), DR ($P = .85$), VAS of back pain ($P = .55$), VAS of leg pain ($P = .83$) and ODI ($P = .68$) were found between 2 groups. After 12-month treatment, there were no significant differences in ISH ($P = .26$), VAS of back pain ($P = .09$) and VAS of leg pain ($P = .96$) between two groups. Significant differences of DR ($P = .02$), ODI ($P = .03$) and adverse events ($P = .00$) were found between 2 groups.

Conclusions: The results of this prospectively study showed that the ball-point slide-type interbody distractor in the posterior reduction and internal fixation produced good outcomes after 12-month treatment. More high quality randomized controlled trials and cases should still be needed to warrant the results of this study.

Abbreviations: CT = computerized tomography, DR = degree of reduction, FBSS = failed back surgery syndrome, ISH = intervertebral space height, MRI = magnetic resonance imaging, ODI = oswestry disability index, PLIF = posterior lumbar interbody fusion, VAS = visual analog scale.

Keywords: lumbar vertebrae, spondylolisthesis, posterior reduction, internal fixation, distractor

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1. Introduction

Spondylolisthesis is a common lumbar disease characterized by the upper vertebral body slipping forward along the inferior vertebral body. When the biomechanical balance of the lumbar spine is compromised, the cauda equina is compressed by the posterosuperior margin of the inferior vertebral body. In addition, the intervertebral space becomes narrower, leading to intervertebral fusion in some cases.

Currently the effective treatment for spondylolisthesis involves posterior decompression, pedicle screw fixation, vertebral slip reduction, and posterior lumbar interbody fusion. The pedicle screw system is instrumentation specifically developed for surgical treatment of patients with spondylolisthesis.[1] And its clinical implementation has been effective at achieving reductions in patients with low-grade isthmic spondylolisthesis.[2] However, osteoporotic patients with mid- to high-grade isthmic spondylolisthesis and extremely narrow intervertebral spaces do not benefit as well from pedicle screw fixation. After surgery, loss of intervertebral space height (ISH) is common in these mid- to high-grade patients, and fractures or loosening of the fixation systems have led to failed back surgery syndrome (FBSS). [3–5]

Although anatomical reduction by pedicle screw fixation has been less effective in patients with mid- to high-grade isthmic spondylolisthesis, there is currently no assistive instrument that has been shown to significantly improve patient outcomes over current methods. As a potential solution for this problem, we sought to improve posterior reduction and internal fixation by designing a ball-point slide-type interbody distractor as a new surgical tool. In a randomized control trial, we used this newly developed instrument in surgeries of 29 patients with spondylolisthesis. We compared their radiologic and clinical results with 30 patients who had undergone posterior reduction and internal fixation using pedicle screw fixation.

2. Materials and methods

2.1. Ethics statement

Study participants voluntarily agreed to participate in the study and provided written informed consent prior to enrollment. The study was approved by the Ethics Committee of the Harrison International Peace Hospital of Hebei Medical University.

2.2. Design

This prospective study was conducted from July 2011 to September 2013 at Harrison International Peace Hospital of Hebei Medical University. Sixty-nine patients with isthmic spondylolisthesis were enrolled in this study. The investigational group patients (N=29) with isthmic spondylolisthesis were randomly enrolled (applying table of random digit) in the study and underwent posterior reduction and internal fixation with a ball-point slide-type interbody distractor. Control group patients (N=30) with isthmic spondylolisthesis were randomly enrolled and received posterior reduction and internal fixation. The follow-up period was 12 months, and all patients' clinical and radiologic data were prospectively analyzed. In this study, all patients, outcome assessors and data analyst were blinded, except the researchers (Fig. 1).

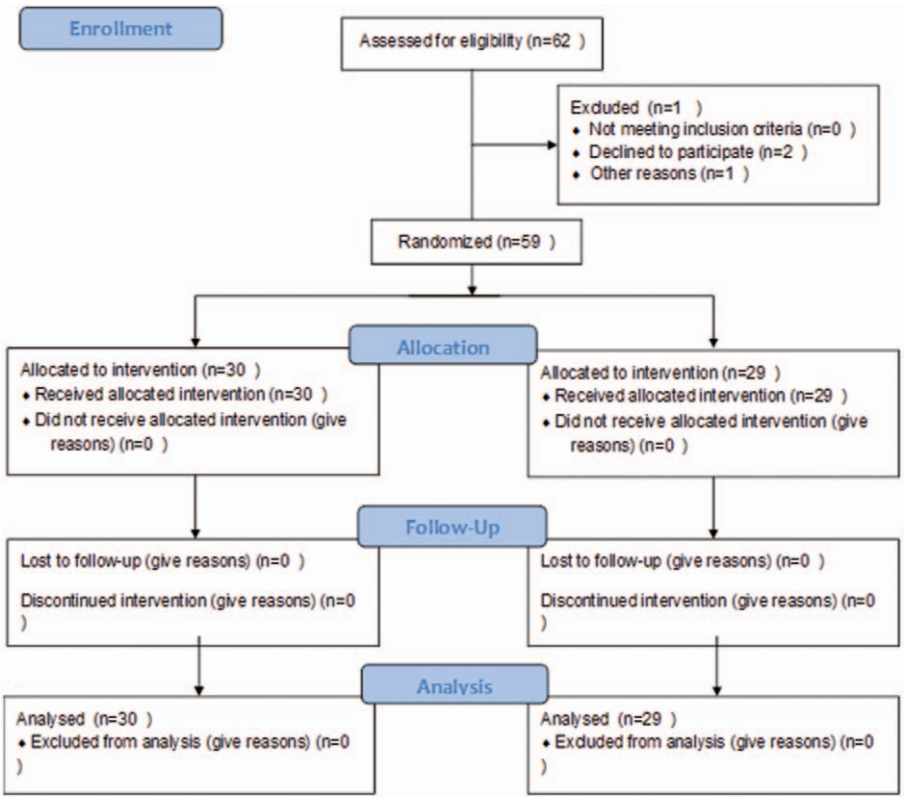

Figure 1. Consort flow diagram.

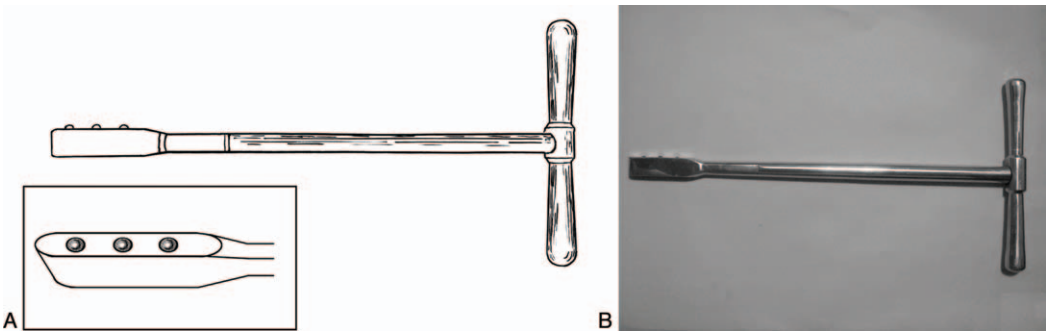

Figure 2. Representative illustration and photograph showing the ball-bearing slide-type interbody distractor. (A) Illustration of the ball-bearing slide-type interbody distractor. The major difference from a normal distractor is the ball-slide on one side which assists the vertebral reduction. (B) Photograph of the ball-bearing slide-type interbody distractor used in surgery.

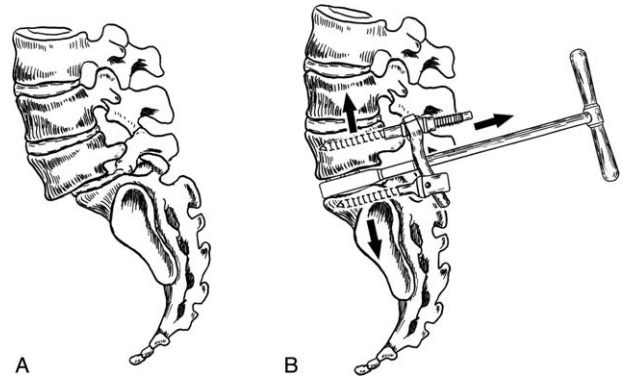

Figure 3. Representative illustrations showing the distraction and reduction of spondylolisthesis with the assistance of the new surgical instrument. (A) Illustration of lumbar spondylolisthesis. (B) The distraction and reduction of spondylolisthesis requires forces acting in three different directions. The arrow indicates the mechanical direction of distraction and reduction. The new surgical instrument plays the role of distraction and auxiliary reduction.

2.3. Inclusion and exclusion criteria

This study included patients aged from 36 to 70 years old. All of them received complete X-ray, CT and MRI examination and were clinically diagnosed of isthmic spondylolisthesis. However, patients were excluded if they had other conditions except the isthmic spondylolisthesis. These conditions included diabetes, heart disease, nephropathy, sequelae of cerebral infarction; or history of trauma, pregnancy, or breast feeding; or received other treatments for isthmic spondylolisthesis during the period of study.

2.4. Surgical technique

All 69 participants in both groups received surgical operation of reduction and posterior lumbar interbody fusion (PLIF). In addition, 29 patients in the investigational group received this surgical operation with a new surgical instrument of ball-point slide-type interbody distractor, while the other 30 patients in the control group received the surgical operation without ball-point slide-type interbody distractor (Figs. 2–5).

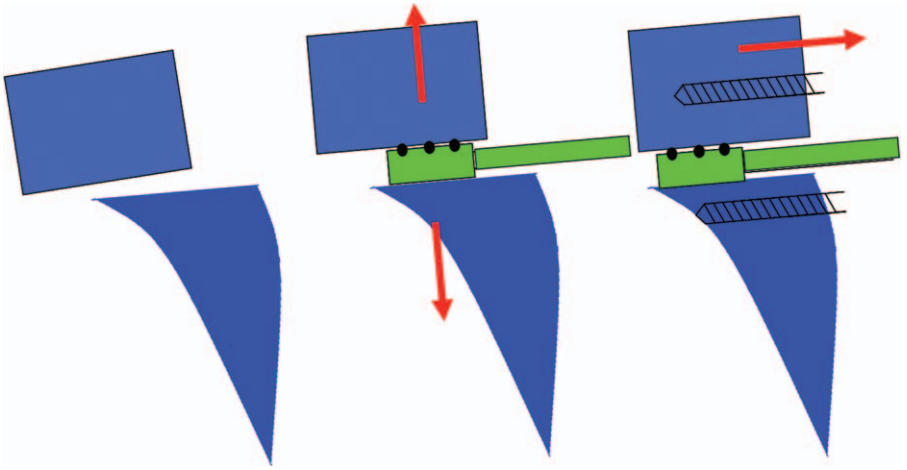

Figure 4. Schematic illustrating the process of distraction and reduction of spondylolisthesis. The arrow indicates the mechanical direction of distraction and reduction. The ball-bearing slide-type interbody distractor produces a large, longitudinally-sustained force and can recover the intervertebral space height. The assisted reduction procedure is then performed.

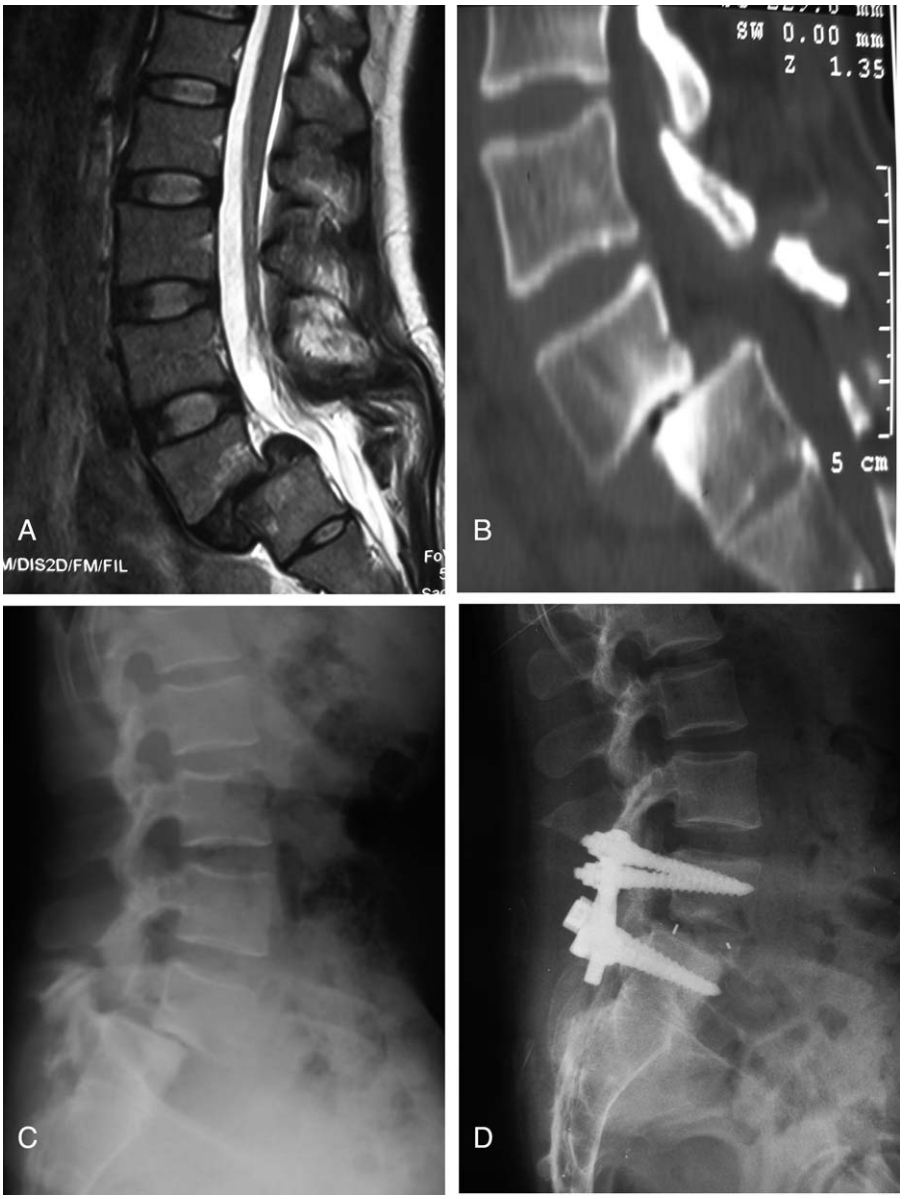

Figure 5. Representative images of the investigational group showing the preoperative and postoperative lumbar spondylolisthesis and spondylolysis. (A) Preoperative MRI image showing the degenerative spondylolisthesis and dural sac compression. (B) Preoperative CT scan showing the intervertebral space was extremely narrow. (C) Preoperative radiograph of the investigational group showing the grade of spondylolisthesis (Grade III° by Meyerding's Grading Method for spondylisthesis). (D) Postoperative radiograph of the investigational group showing the grade of spondylolisthesis (Grade I° by Meyerding's Grading Method). Patients almost achieved anatomic reduction.

2.5. Postoperative care

Patients in both groups were allowed to sit up or walk with the use of a lumbosacral orthosis between 24 and 48 hours after surgery. Patients were braced with the lumbosacral orthosis for a 3-month period.

2.6. Radiologic and clinical evaluation

The efficacy endpoints consisted of intervertebral space height (ISH),[6,7] anterior displacement (AD),[8,9] Visual Analog Scale (VAS) and the Oswestry Disability Index (ODI).[10] All these endpoints were measured before and after 12-month treatment. Additionally, any expected and unexpected adverse events were also assessed in this study.

2.7. Statistical analysis

The Wilcoxon rank sum test was performed to detect differences in the heights of intervertebral spaces. Two-sample t test was performed to compare the reduction rates between 2 groups. For the statistical analysis of the VAS and ODI scores, 2-sample t tests and Wilcoxon rank sum tests were used. Statistical significance was defined as a probability value of less than .05 (i.e., $P < .05$). Computerized statistical analysis was performed using computer

Table 1

Characteristics comparison between 2 groups before the study.

Characteristics	Investigational group (n = 29)	Control group (n = 30)	*P* value
Age (yr)	48.5 (10.9)	52.3 (9.7)	.53
Gender			
Male	6 (20.7)	8 (26.7)	.33
Female	23 (79.3)	22 (73.3)	.26
Race (Chinese)	29 (100.0)	30 (100.0)	.62
Weight (kg)	68.3 (10.1)	69.5 (10.7)	.56
Smoking history	9 (31.0)	10 (33.3)	.81
Drinking history	7 (24.1)	8 (26.7)	.36
Meyerding method of measuring the degree of slip			
II°	17 (58.6)	18 (60.0)	.76
III°	10 (34.5)	11 (36.7)	.58
IV°	2 (6.9)	1 (3.3)	.11
Segment treated			
L4-L5	3 (10.3)	5 (16.7)	.29
L5-S1	26 (89.7)	25 (83.3)	.83

Data are present as mean ± standard deviation or number (%).

statistical software for Windows (version 17.0, SPSS Inc., Chicago, IL).

3. Results

The comparison of all characteristics between 2 groups before this study is showed in Table 1. And there were not significant statistical differences according to all characteristic values between 2 groups prior to surgical operation in this clinical research (Table 1).

Before the surgical operation, no significant differences in all effect endpoints of ISH ($P = .72$, Table 2), AD ($P = .85$, Table 3), VAS score for back pain ($P = .55$, Table 4), VAS score for leg pain ($P = .83$, Table 5) and ODI ($P = .68$, Table 6) were found between 2 groups.

After 12-month follow-up, there were no significant differences in ISH ($P = .26$, Table 2), VAS score for back pain ($P = .09$, Table 4) and VAS score for leg pain ($P = .96$, Table 5) between 2 groups.

Statistically significant differences of AD ($P = .02$, Table 3) and ODI ($P = .03$, Table 6) were observed in the investigational group compared to control group.

After 12-month follow-up, no fractures or loosening of the fixation system were observed in investigational group in this study. At the 3-month follow-up visit, 1 case in the control group presented with a loosening of the pedicle screw. At the 12-month follow-up visit, 1 case in the control group presented with a fracture of the pedicle screw. There were significant differences of adverse events between 2 groups ($P = .00$).

Table 2

Comparison of intervertebral space height between 2 groups.

ISH (mm)	Investigational group (n = 29)	Control group (n = 30)	*P* value
Preoperative	5.5 (1.7)	6.0 (1.9)	.72
Follow-up	11.4 (1.3)	10.0 (1.2)	.65
Change from prior-treatment	5.9 (1.2, 7.1)	4.0 (1.1, 6.5)	
Difference between two groups		1.9 (0.6, 2.1)	.26

Data are present as mean ± standard deviation or range.

Table 3

Comparison of anterior displacement between two groups.

Anterior displacement	Investigational Group (n = 29)	Control Group (n = 30)	*P* value
Preoperative	46.0 (16.6)	46.7 (15.1)	.85
Follow-up	9.9 (4.4)	18.4 (11.1)	.04
Change from prior-treatment	−36.1 (−42.2, −22.3)	−28.3 (−36.2, −23.5)	
Difference between 2 groups		−7.8 (−9.0, −5.1)	.02

Data are present as mean ± standard deviation or range.

Table 4

Comparison of VAS score (Back pain) between 2 groups.

VAS score (Back)	Investigational group (n = 29)	Control group (n = 30)	*P* value
Preoperative	7.2 (2.4)	6.9 (2.5)	.55
Follow-up	2.2 (1.6)	3.3 (2.1)	.16
Change from prior-treatment	5.0 (1.5, 6.2)	3.6 (1.2, 5.1)	
Difference between 2 groups		1.4 (0.7, 1.9)	.09

Data are present as mean ± standard deviation or range.

Table 5

Comparison of VAS score (Leg pain) between 2 groups.

VAS score (leg)	Investigational group (n = 29)	Control group (n = 30)	*P* value
Preoperative	6.6 (1.9)	7.0 (1.8)	.83
Follow-up	1.7 (1.5)	2.0 (1.2)	.79
Change from prior-treatment	4.9 (3.5, 6.3)	5.0 (3.3, 6.0)	
Difference between two groups		0.1 (0.0, 0.3)	.96

Data are present as mean ± standard deviation or range.

Table 6

Comparison of ODI between 2 groups.

ODI (%)	Investigational group (n = 29)	Control group (n = 30)	*P* value
Preoperative	58.8 (19.1)	55.9 (14.7)	.68
Follow-up	22.5 (13.6)	32.1 (12.2)	.11
Change from prior-treatment	36.3 (17.2, 44.9)	23.8 (11.2, 37.6)	
Difference between 2 groups		12.5 (3.2, 9.1)	.03

Data are present as mean ± standard deviation or range.

4. Discussion

Previous studies have reported that the effective treatment for spondylolisthesis is posterior decompression, pedicle screw fixation, slip reduction, and PLIF.[1,2,10] However, the patients with mid- to high-grade isthmic spondylolisthesis frequently have extremely narrow intervertebral spaces, and the reduction will be particularly difficult.[11–14] For this reason, some of these difficult

cases are limited to fixing and fusing the vertebral bodies in situ. Many studies attributed the poor clinical results to the mid- to high-grade of isthmic spondylolisthesis and the severe adhesion caused by scar tissue which is difficult to remove.[15–19] Moreover, in cases of mid- to high-grade isthmic spondylolisthesis and extremely narrow intervertebral spaces, it is difficult to distract and lift the vertebral bodies by the pedicle screw system alone. Meanwhile, the pressure of distract and lift results in loosening of the pedicle screw, which can cause vertebral fractures. [20]

To solve this problem, the ball-point slide-type interbody distractor was invented by our research group. And the device can insert into the disc space, directly bear the loads from the intervertebral distraction. In addition, the effective distraction is the basis for further reduction (Fig. 6). Just as important, enough bone graft material and the suitable cage can promote fusion. And the satisfactory fusion can prevent the movement of the cage.[21] Furthermore, with intervertebral cage, the better fusion can maintain lumbar stability and effectively prevent fracture of the fixation system. [22,23]

The present study compared the effect of ball-point slide-type interbody distractor and traditional surgery for the treatment of patients with mid- to high-grade isthmic spondylolisthesis. The results of the present study demonstrated that after 12-month treatment, patients in the investigational group did not exert better effect endpoints in ISH ($P = .26$), VAS of back pain ($P = .09$) and VAS of leg pain ($P = .96$) than patients in the control group. However, better effects of DR ($P = .02$), ODI ($P = .03$) and adverse events ($P = .00$) in the investigational group were observed. The results indicated that ball-point slide-type interbody distractor may benefit for patients with mid- to high-grade isthmic spondylolisthesis. Especially, it effectively releases the loss of DR after surgery.

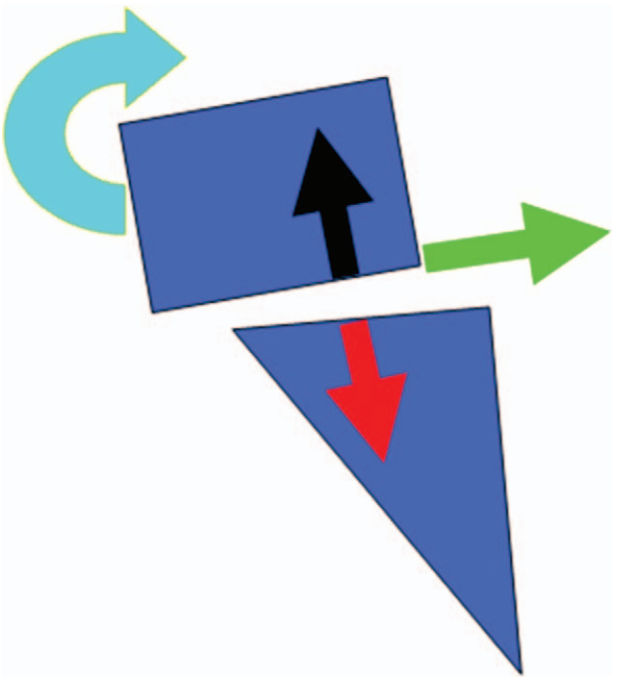

Figure 6. Representative illustrations showing the distraction and reduction forces in different directions. The arrow indicates the mechanical direction of distraction and reduction. The forces in three different directions: the interbody distraction force acts on the upper and lower vertebra, the traction force acts on the slip vertebra. And the rotary force on the upper vertebra.

In addition, traditional surgical treatments only apply the pedicle screw system to complete reducing process, and the whole procedure is performed on the rough "bone-bone" interface.[24,25] This is because the extremely narrow intervertebral space and the hyperostosis or osteosclerosis of the upper and lower end plate produce friction and abnormal activity.[26] In this study, the ball-point slide-type interbody distractor is uesd to treat the mid- to high-grade spondylolisthesis, and the process can perform on the smooth "bone-ball" interface.

This study has several limitations. First, the sample size is small and more large scale studies are needed to warrant the results of this study. Second, the follow-up time is short and long-term observation of surgical effect needs to be completed. Therefore, future studies should avoid those limitations.

5. Conclusion

The application of a ball-point slide-type interbody distractor in the posterior reduction and internal fixation has a good clinical outcome for mid- to high-grade isthmic spondylolisthesis. More high quality randomized controlled trials and cases should still be needed to warrant the results of this study.

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Author contributions

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Writing – review & editing: Pengfei Li, Zongmao Zhao, Nan Jia, Litao Wang, Zhaoshen Sun, Xianhui Jin.

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